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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,790

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Motoyuki Tagashira

TAGASHIRA2

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EXAMINER

RAO, SAVITHA M

ART UNIT

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1614

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12/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,790	Applicant(s) TAGASHIRA ET AL.	
	Examiner SAVITHA RAO	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08/20/2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) 2-5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-5 are pending. Receipt and consideration of Applicants' amended claim set and remarks/arguments mailed on August 20th 2008 is acknowledged. Claims 1 is amended and 2-5 are withdrawn.

Applicants' arguments, filed 08/20/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

This rejection is necessitated by the newly submitted claims filed on 07/16/2008.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites "synthetic gel adsorbent" in the last line. The gel in the specification is disclosed as filed as "adsorbing polyphenols". Accordingly, the

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claimed synthetic gel adsorbent is very broadly defined which is not in the original disclosures and thereby constitutes new matter.

Claim Rejections - 35 USC § 102(b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Rejection of Claim 1 under 35 U.S.C. 102(b) as being anticipated by Motoyuki et al (Biosci. Biotech. Biochem. 61 (2) 332-335 (1997)) **is maintained** for reasons of record as restated below.

Instant claims 1 is drawn to a process for producing hop bract polyphenol extracting hop bract with an aqueous alcohol solution, concentrating the extract to give a residual alcohol concentration of 2 v/v% or less, and purifying the concentrate.

Motoyuki discloses preparation of the hop bract polyphenols where the bracts were extracted with 2 liters of 30% ethanol aqueous solution. After filtration and evaporation of the ethanol, the extract was lyophilized to give a light-green residue. The residue was purified by dissolving in 1 liter of distilled water and passing it through a styrene-divinylbenzene resin column, for 60 minutes. The column was washed with water and polyphenol was eluted with ethanol aqueous solution stepwise. After evaporation of the ethanol, each fraction was lyophilized to give light-brown powder of hop bract polyphenol (page 332, Materials and Methods, left column, last paragraph).

With regards to the instant claim 1 limitation wherein the residual alcohol concentration was 2% v/v before the final purification method, Motoyuki is silent as to the final alcohol content of his preparation. However, since the procedure for preparation of the Hop Bract polyphenols is identical to the instantly claimed method and additionally, Motoyuki's process involves evaporation and lyophilization of the extracted polyphenol before it is purified, any traces of alcohol if present would be as low as or lower than that instantly claimed. Absence of any evidence to the contrary, prior art hop bract polyphenol would exhibit the same properties as that claimed in the instant claim 1. It is incumbent upon the applicant to provide evidence or comparative data to the contrary.

Accordingly claim 1 is anticipated by Motoyuki et al.

Response to Applicant's argument filed on 08/20/2008

Applicant traverse the above rejection with an argument that the reference do not teach the purification step by either filtering and/or centrifuging the concentrate before purification with the synthetic gel type adsorbent.

Examiner acknowledges Applicant's traversal but do not find it persuasive.

Motoyuki' procedure discloses the filtration step, prior to the column purification step. Motoyuki discloses that the extracted bract with aqueous ethanol solution was **filtered** and lyophilized to form a residue which was dissolved in water before passing through a styrene-divinylbenzene column as stated above. Accordingly, Motouki

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teaches the filtration step prior to the column purification step and thereby anticipates claim 1.

Response to Applicant's argument on unexpected results:

Examiner has considered unexpected results disclosed by the Applicant but has found them to be unpersuasive.

It is generally known by one of ordinary skill in the art that extraction of active principles from plant materials involves separation of the unwanted solid material from the fraction comprising the active principle. Separation using centrifugation and filtration for this purposes before the product goes through additional purification steps is well known in the art. Greater care in achieving the initial separation from the unwanted material before column purification, higher the yield of the active material as the additional separation step prevents the column clogging with unwanted materials and thereby provides purer material of higher yield.

The unexpected results claimed by the applicant for example 1 (instant method) to comparative example 2 (Motoyoki's method) (page 10,line 5-9) in terms of yield is 83.7 to 77.2% respectively and for the insoluble glucan level (Fig.1 in the Drawings) is 0.2 to 0.35 respectively. The fold increase in yield is just over 5 and less than 10% which is well within the margin of error. The fold improvement in the insoluble glucan level is just 0.15 fold which again is well within the margin of error in routine experimentation.

Accordingly, applicant's argument of unexpected results is not persuasive.

Additionally, Examiner would like to point out to the Applicant, that unexpected results argument cannot be used to overcome an anticipation rejection since the claimed invention is already taught in the prior art and would essentially have the same properties and performance characteristics as the instantly claimed invention.

Conclusion

Claim 1 is rejected. No claims are allowed

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-5315. The examiner can normally be reached on Mon-Fri 7.00 am to 4.00 pm..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAVITHA RAO/

Examiner, Art Unit 1614

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614